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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,788	04/25/2001	Per-Olof Larsson	PL9824	3855

22840 7590 08/09/2002

AMERSHAM BIOSCIENCES  
PATENT DEPARTMENT  
800 CENTENNIAL AVENUE  
PISCATAWAY, NJ 08855

EXAMINER

VO, HAI

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 08/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-6

<b>Office Action Summary</b>	<b>Application No.</b> 09/763,788	<b>Applicant(s)</b> LARSSON ET AL.	
	<b>Examiner</b> Hai Vo	<b>Art Unit</b> 1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                 | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: _____                                    |

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19, drawn to a composite material.

Group II, claim(s) 20-30, drawn to a separation method of using a composite material.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: claim 1 is obvious over WO 93/19115 (see rejections below). As the recited structure does not make a contribution over the prior art, unity of invention is lacking and restriction is appropriate.

2. During a telephone conversation with Royal N. Ronning on 06/28/2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Objections***

3. Claims 1-19 are objected to because of the following informalities: the phrase "characterized in that" should be changed to -- wherein -- or -- comprising --. In claim 1, line 7, the "," after "is" should be deleted. In claim 18, line 2, the term "a" needs to be changed to -- the --. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 10, and 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 10, 12, 14, and 17, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 13-19 provide for the use of the composite material, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-19 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim

under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Lihme et al (US 5,866,006). WO'115 teaches a porous polysaccharide having a net work of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising large diameter flow through pores (abstract). WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores. However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 is silent as to the secondary component of the composite material. Lihme discloses a conglomerate and the use of the conglomerate as a carrier or substrate material in a chromatographic procedures (column 8, line 62 et seq.). It would have been obvious to one having ordinary skill

in the art at the time the invention was made to employ a conglomerate as the secondary component of the porous material in WO'115 motivated by the desire to maximize the chromatographic performance of the super-porous material because the elasticity, mechanical strength, pore sizes and biocompatibility of the conglomerate can be controlled independently of the density.

With regard to claims 3-5, since the conglomerate of Lihme acts as the filler is mixed with the super-porous material of WO'115, it is the examiner's position that the conglomerate would be expectedly present anywhere in the matrix, i.e., outside the super-pores but inside the main component's gel phase or in the super-pores of the main component or present in both the super-pores and in the gel-phase of the main-component.

With regard to claims 6-8, and 10, WO'115 discloses the super-porous material being coupled with various ligands (examples 8, 9 and 12).

With regard to claim 9, Lihme discloses the ligand being coupled with the conglomerate (column 18, lines 39-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the ligand with the conglomerate motivated by the desire to keep the desired functions of the active substance intact or may be reestablished before use.

With regard to claim 11, WO'115 discloses the super-porous material having the macropores with an average pore diameter in the gel phase from 5 to 100 microns (page 4). Lihme teaches the conglomerate having the pore size from 50-500 microns (column 14, line 53). It would have been obvious to one having ordinary skill in the

art at the time the invention was made to employ a conglomerate having the average pore size greater than that of the macropore in the gel phase of the main component motivated by the desire to control the flow rate of the separation.

With regard to claim 12, WO'115 discloses the porous material being prepared as a continuous bed (page 6).

With regard to claim 13, WO'115 discloses the super-porous material being used in affinity chromatography (example 14).

With regard to claim 14-19, Lihme reads on the claim limitations (column 8, line 62 et seq.). It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the composite material of WO'115 as modified by Lihme for variety applications as set forth in the claims because the composite material would be a, desirable, excellent solid phase matrix, carrier or substrate material in variety applications.

8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Schaeffer et al (US 4,111,838). WO'115 teaches a porous polysaccharide having a net work of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising large diameter flow through pores (abstract). WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores. However, the pore arrangement would inherently be present since the

WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 is silent as to the secondary component of the composite material. Schaeffer discloses a chromatographic material comprising an inorganic support-polysaccharide particle matrix. The matrix comprises an inorganic support that has a high surface density of hydroxyl groups and covalently attached to polysaccharide particles (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inorganic support as taught in Schaeffer as the secondary component of the porous material in WO'115 motivated by the desire to obtain a chromatographic material that provides columns with high flow rates and high degree of purification.

With regard to claims 3-5, since the inorganic support of Schaeffer is mixed with the super-porous material of WO'115, it is the examiner's position that the inorganic support would be expectedly present anywhere in the matrix, i.e., outside the super-pores but inside the main component's gel phase or in the super-pores of the main component or present in both the super-pores and in the gel-phase of the main-component.

With regard to claims 6-8, and 10, WO'115 discloses the super-porous material being coupled with various ligands (examples 8, 9 and 12).

With regard to claim 9, Schaeffer discloses the ligand being coupled with the inorganic support (column 4, lines 3-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the ligand with



the inorganic support motivated by the desire to control the multipoint attachments of the proteins.

With regard to claim 11, WO'115 discloses the super-porous material having the macropores with an average pore diameter in the gel phase form 5 to 100 microns (page 4). Schaeffer teaches the inorganic support having the pore size from 100-1000 microns (column 3, line 56). See obviousness rational with respect to claim 11 in the paragraph no. 7.

With regard to claim 12, WO'115 discloses the porous material being prepared as a continuous bed (page 6).

With regard to claim 13, WO'115 discloses the super-porous material being used in affinity chromatography (example 14).

With regard to claims 14-16, it has been held that a recitation with respect to the manner in which a claimed composite material is intended to be employed does not differentiate the claimed composite material from a prior art super-porous material satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

9. Claims 1-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Manganaro et al (US 5,155,144). WO'115 teaches a porous polysaccharide having a net work of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase is the superpore-forming phase comprising

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large diameter flow through pores (abstract). WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores. However, the pore arrangement would inherently be present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 is silent as to the secondary component of the composite material. Manganaro discloses a microporous sheet containing a selective-binding matrix formed from polyvinyl chloride beads and polysaccharide (example 1). See obviousness rational with respect to claim 1 in the paragraph no. 7.

With regard to claims 3-5, since the polyvinyl chloride beads of Manganaro is mixed with the super-porous material of WO'115, it is the examiner's position that the polyvinyl chloride beads would be expectedly present anywhere in the matrix, i.e., outside the super-pores but inside the main component's gel phase or in the super-pores of the main component or present in both the super-pores and in the gel-phase of the main-component.

With regard to claims 6-8, and 10, WO'115 discloses the super-porous material being coupled with various ligands (examples 8, 9 and 12).

With regard to claim 9, Manganaro discloses the porous sheet being capable of selectively binding targeted biological materials via ligand binding sites (column 3, lines 25-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the ligand with the polyvinyl chloride beads

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motivated by the desire to keep the desired functions of the active substance intact or may be reestablished before use.

With regard to claim 11, WO'115 discloses the super-porous material having the macropores with an average pore diameter in the gel phase form 5 to 100 microns (page 4). Manganaro teaches the polyvinyl chloride beads having the pore size of 140 microns (column 12, line 2). See obviousness rational with respect to claim 11 in the paragraph no. 7.

With regard to claim 12, WO'115 discloses the porous material being prepared as a continuous bed (page 6).

With regard to claims 13-15 and 18, WO'115 discloses the super-porous material being used in an affinity chromatography and a bio-reactor (column 2, lines 55-62).

With regard to claim 16, see intended-use rational with respect to claims 14-16 in the paragraph no. 8.


### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (703) 605-4426. The examiner can normally be reached on Monday to Friday, 8:30 to 5:00 (EAST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (703) 308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

HV  
August 2, 2002



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